

PATENT  
ATTORNEY DOCKET NO. 06275/004001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kjell G.E. Bäckström et al.      Art Unit: 1817  
Serial No.: 08/265,237      Examiner: Prickril, B.  
Filed : June 23, 1994  
Title : COMPOSITIONS FOR INHALATION

Assistant Commissioner for Patents  
Washington, DC 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO 1449, copies of which are enclosed.

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action or a Notice of Allowance. A check for \$230 in payment of the late submission fee of \$1.17(p) is enclosed. Please apply any additional charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

March 28, 1997

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Date of Deposit

March 31, 1997

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Charles A. Woodbury  
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| SUBSTITUTE FORM PTO-1449<br>(MODIFIED)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |                     | ATTY. DOCKET NO.: 062 004001           |       | SERIAL NO.: 08/265,237 |                               |
|---|----|--|---------------------|--|-------|------------------------|-------------------------------|
| SUPPLEMENTAL INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(Use several sheets if necessary)<br><br>(37 CFR 1.98(b))  |    |  |                     | APPLICANT: Kjell G.E. Bäckström et al. |       |                        |                               |
|   |    |  |                     | FILING DATE: June 23, 1994             |       | GROUP: 1806            |                               |
| U.S. PATENT DOCUMENTS   |    |  |                     |  |       |                        |                               |
| EXAMINER<br>INITIAL   |    | PATENT NUMBER  | ISSUE<br>DATE       | PATENTEE                               | CLASS | SUBCLASS               | FILING DATE<br>IF APPROPRIATE |
|   | AA | 4 8 4 7 2 9 8  | Jul 11 1989         | Alexander et al.                       |       |                        |                               |
|   | AB | 4 9 9 4 4 3 9  | Feb 19 1991         | Longenecker et al.                     |       |                        |                               |
|   | AC | 5 0 0 6 3 4 3  | Apr 9 1991          | Benson et al.                          |       |                        |                               |
|   | AD | 5 1 2 2 1 2 7  | Jun 16 1992         | Stanley                                |       |                        |                               |
|   | AE | 5 1 7 9 0 7 9  | Jan 12 1993         | Hansen et al.                          |       |                        |                               |
|   | AF | 5 2 0 0 3 9 3  | Apr 6 1993          | Weiner                                 |       |                        |                               |
|   | AG | 5 5 1 4 6 7 0  | May 7 1996          | Friedman et al.                        |       |                        |                               |
| FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION  |    |  |                     |  |       |                        |                               |
|   |    | DOCUMENT NUMBER  | PUBLICATION<br>DATE | COUNTRY OR<br>PATENT OFFICE            | CLASS | SUBCLASS               | TRANSLATION<br>YES NO         |
|   | AH | WO90/07333   | 12/07/90            | PCT                                    |       |                        |                               |
|   | AI | WO92/08446   | 29/05/92            | PCT                                    |       |                        |                               |
|   | AJ | EP 0 023 359 A2  | 04/02/81            | Europe                                 |       |                        |                               |
|   | AK | GB 837,465   | 15/06/60            | Great Britain                          |       |                        |                               |
|   | AL | DK DD 261 096 A1   | 19/10/88            | Germany                                |       |                        | X                             |
| OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)   |    |  |                     |  |       |                        |                               |
|   | AM | Almer et al., Insulin Inhalation - At Last A Break-Through, Diabetes Res. Clin. Pract. 5:S163-POS-001-169, 1988.   |                     |  |       |                        |                               |
|   | AN | Bjork, Starch Microspheres as a Nasal Delivery System for Drugs, ACTA Univ. Upsaliensis, UPPSALA, Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy, 103: parts 1-5, 1993. |                     |  |       |                        |                               |
|   | AO | Chandler et al., Nasal Absorption in Rats. II. Effect of Enhancers on Insulin Absorption and Nasal Histology, Int'l J. Pharmaceutics, 76:61-70, 1991.  |                     |  |       |                        |                               |
|   | AP | Cutie et al., The Role of Dispersing Agents in Inhalation and Intranasal Aerosol Suspensions, Aerosol Age, pp. 52-54, 1985.  |                     |  |       |                        |                               |
|   | AO | Dahlback et al., Regional Administration of Drugs to the Rabbit Respiratory Tract, Effects on Absorption, J. Aerosol Medicine, 7th International Congress on Aerosols in Medicine, Sept. 1988, p. 222. |                     |  |       |                        |                               |
|   | AR | Dahlback et al., Deposition of Tracer Aerosols in the Rabbit Respiratory Tract, J. Aerosol Sci., Vol. 18, No. 6. pp. 733-736, 1987.  |                     |  |       |                        |                               |
| EXAMINER  |    |  |                     | DATE CONSIDERED                        |       |                        |                               |
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |  |                     |  |       |                        |                               |

Substitute Disclosure Form (PTO-1449)

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| SUBSTITUTE FORM PTO-1449<br>(MODIFIED)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |                     | ATTY. DOCKET NO.: 06 004001            |       | SERIAL NO.: 08/265,237 |                               |
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| EXAMINER<br>INITIAL   |    | PATENT NUMBER  | ISSUE<br>DATE       | PATENTEE                               | CLASS | SUBCLASS               | FILING DATE<br>IF APPROPRIATE |
|   | BA |  |                     |  |       |                        |                               |
|   | BB |  |                     |  |       |                        |                               |
| FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION  |    |  |                     |  |       |                        |                               |
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|   | BC |  |                     |  |       |                        |                               |
| OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)   |    |  |                     |  |       |                        |                               |
|   | BD | Gordon et al., Nasal Absorption of Insulin: Enhancement by Hydrophobic Bile Salts, Proc. Nat'l. Acad. Sci. USA, 82:7419-23, 1985.  |                     |  |       |                        |                               |
|   | BE | Lee et al., Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption, Critical Reviews in Therapeutic Drug Carrier Systems, 8(2):91-192, 1991.        |                     |  |       |                        |                               |
|   | BF | Ruñ, Diabetics May Not Need Their Insulin Shots, article in Sydsvenska (Dagbladet), Monday, June 12, 1989.<br>(English translation attached)                                       |                     |  |       |                        |                               |
|   | BG | Schanker et al., Species Comparison of Drug Absorption from the Lung After Aerosol Inhalation or Intratracheal Injection, Drug Metabolism & Disposition, Vol. 14, pp. 79-88, 1986. |                     |  |       |                        |                               |
|   | BH | Wearley, Recent Progress in Protein and Peptide Delivery by Noninvasive Routes, Critical Reviews in Therapeutic Drug Carrier Systems, 8(4):331-94, 1991.                           |                     |  |       |                        |                               |
|   | BI | Yoshida et al., Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form, J. Pharm. Sci. 68:670, 1979.  |                     |  |       |                        |                               |
| EXAMINER  |    |  |                     | DATE CONSIDERED                        |       |                        |                               |
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PATENT  
ATTORNEY DOCKET NO.: 06275/004001

The Patent and Trademark Office date stamp sets forth the date of receipt of:

Applicant or Patentee Kjell G.E. Backstrom et al.No. (Application, Appeal, Interference, Patent, Reexam) 08/265,237Filing or Issue Date June 23, 1994Title COMPOSITIONS FOR INHALATION

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**FISH & RICHARDSON P.C.**  
225 FRANKLIN STREET  
BOSTON, MA 02110

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